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RE: Single Maintenance and Reliever Therapy (SMART) Alternative for Patients with Asthma

Dear Dr. <<Name>>:

Thank you for providing quality care for Texas Fee-For-Service (FFS) Medicaid patients. The content of this letter has been approved by the Texas Drug Utilization Review (DUR) Board, whose function is to promote safe and cost-effective drug therapy and provide opportunities for continuous improvement of care.

The U.S. Department of Health and Human Services, Centers for Disease Control and Prevention found in 2019 that asthma accounted for 1.5 million emergency department visits¹. Both the Global Initiative for Asthma and National Heart, Lung and Blood Institute recently updated their guidelines on asthma management and recommend the use of single maintenance and reliever therapy (SMART or MART) for some people with asthma. SMART involves using one inhaler consisting of controller and reliever therapy in the form of inhaled corticosteroid (ICS) and formoterol, whereas conventional therapy consists of using two separate inhalers, one as controller and one as reliever. SMART is associated with a reduced risk of acute asthma exacerbations, emergency department visits, and hospitalizations when compared to conventional therapy^{2,3}. More information can be found in the following clinical guidelines:

- 2022 Global Initiative for Asthma: Global Strategy for Asthma Management and Prevention https://ginasthma.org/wp-content/uploads/2022/07/GINA-Main-Report-2022-FINAL-22-07-01-WMS.pdf
2020 Focused Updates to the Asthma Management Guidelines: A Report from the National Asthma Education and Prevention Program Coordinating Committee Expert Panel Working Group: https://www.nhlbi.nih.gov/resources/2020-focused-updates-asthma-management-guidelines

You have been selected to receive this mailing based on having one or more patients ≥ 12 years old with asthma who may be overutilizing their short-acting beta2-agonist (SABA) by filling more than 3 in the last 180 days. Patients who had COPD or cystic fibrosis were eliminated. Overutilization of SABA could indicate that their asthma is uncontrolled and be a candidate for SMART. We acknowledge that not all patients maybe be a candidate for SMART therapy based on additional clinical factors not apparent in claims data. We also acknowledge that your medical specialty may be a contributing factor in placing you at a higher percentage of prescribing SABA; however, you may still find the information provided useful to your practice. The total Texas Medicaid Fee-For-Service performance indicators for patients ≥ 12 years old who have opportunities to decrease SABA use are shown in the table below.

Total Texas Medicaid FFS Specific Data

Table with 2 columns: SMART Indicator Summary, Number of Providers*. Row 1: Promote optimization of asthma therapy in patients ≥ 12 years old who may be overutilizing SABA, 214

*Based on data through 03/03/2023

We acknowledge that there may be clinical variables influencing an individual patient's management that are not apparent in claims data. However, we believe the issues identified may assist you in caring for your patient(s). It is possible that your license number may have been inadvertently assigned to the claim as an error at the pharmacy during the billing process. **Also, some prescribed medications as well as some recommended laboratory monitoring or physical examinations may not appear on the patient's profile because they may have been privately purchased or were not billable to Medicaid Services.** We thank you for reviewing this information and caring for Texas Medicaid patients, and we welcome the opportunity to discuss any comments or concerns you may have about our quality management program. Please feel free to call our office at 1-866-923-7208 with questions or concerns. If your mailing address is incorrect, it must be updated through the Texas Medical Board online at <http://www.tmb.state.tx.us/page/change-address>.

Sincerely,

Medicaid Drug Use Review Board
Vendor Drug Program H-630

Single Maintenance and Reliever Therapy (SMART or MART) Indicator Summary

Promote optimization of asthma therapy in patients ≥ 12 years old who may be overutilizing SABA:

- High SABA use ($\geq 3 \times 200$ -dose canisters/year) is associated with increased risk of exacerbations as well as increased mortality particularly if ≥ 1 canister is being used per month. Increasing use of SABA or use > 2 days a week for symptom relief (not prevention of exercise-induced bronchoconstriction) generally indicates inadequate control and may require a step up in treatment.^{2,3}
- The focused updates to the asthma guidelines by the National Asthma Education and Prevention Program Coordinating Committee as well as the guidelines by the Global Initiative for Asthma recommend use of a single inhaler containing the combination of an inhaled corticosteroid and formoterol for certain adults and children in steps 3 and 4 of asthma management for improved efficacy, ease of use (administered in a single inhaler than two separate inhalers), and perhaps safety due to reduced systemic corticosteroid exposure.^{2,3}
- Budesonide-formoterol can now be prescribed as both a controller and reliever for certain people, as it combines an ICS to help reduce inflammation in the lungs and formoterol, a long-acting bronchodilator with rapid onset to help open the airways. While SMART might not be necessary for individuals whose asthma is well controlled on conventional therapy, studies show that people on SMART have fewer unplanned visits to the doctor's office when compared to standard asthma therapy. The studies demonstrating reduced exacerbations enrolled individuals with a severe exacerbation in the prior year. The results suggest that such individuals are particularly good candidates for SMART to reduce exacerbations, emergency department visits, and hospitalizations.²
- Most SMART clinical trials were in adults and adolescents (aged ≥ 12 years) and used budesonide-formoterol 160/4.5 μg , one inhalation once or twice daily (step 3, low dose) or two inhalations twice daily (step 4, medium dose). For both steps 3 and 4, patients take additional inhalations of budesonide-formoterol 160/4.5 μg , one inhalation as needed for symptom relief, up to a maximum of 12 total inhalations in any single day (delivering 54 μg formoterol) (See Table 1).^{2,3,4}
- No differences have been documented in harms between this type of therapy and the comparators [ICS or ICS-long acting bronchodilator combinations (LABA)] in individuals aged 12 years and older. The reductions in exposure to oral corticosteroids and to ICS treatment in most studies suggest that SMART might reduce future corticosteroid-associated harms.²
- The efficacy and safety of other ICS-LABA besides budesonide-formoterol and beclometasone-formoterol for SMART have not been studied.⁴
- ICS-formoterol should not be used as quick-relief therapy in individuals using a different ICS-LABA as maintenance therapy.²
- A one-month inhaler supply of ICS-formoterol that is sufficient for maintenance therapy may not last a month if the inhaler is also used for relief therapy. Providers, individuals with asthma, pharmacists, and payers need to be aware of this possibility.²
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Table 1. Practical doses for SMART based on the recommendations from the National Asthma Education and Prevention Program Coordinating Committee and published studies^{2,3,4}

Age group	Budesonide-Formoterol	DOSING				Maximum Dose/Day*
		Step 3		Step 4		
		Maintenance	Relief	Maintenance	Relief	
≥ 12 years	160/4.5 μg delivered dose	One inhalation once or twice daily	One inhalation as needed	Two inhalations twice daily	One inhalation as needed	12 inhalations

* Total daily inhalations equals maintenance therapy doses plus as-needed relief doses in a given day

References:

1. Agency for Healthcare Research and Quality. (2023). Healthcare Cost and Utilization Project 2019 Healthcare Use Data. U.S. Department of Health and Human Services, Centers for Disease Control and Prevention. <https://www.cdc.gov/asthma/national-surveillance-data/healthcare-use.htm>. Accessed March, 2023
2. Expert Panel Working Group of the National Heart, Lung, and Blood Institute (NHLBI) administered and coordinated National Asthma Education and Prevention Program Coordinating Committee (NAEP PCC), Cloutier MM, Baptist AP, et al. 2020 Focused Updates to the Asthma Management Guidelines: A Report from the National Asthma Education and Prevention Program Coordinating Committee Expert Panel Working Group [published correction appears in J Allergy Clin Immunol. 2021 Apr;147(4):1528-1530]. J Allergy Clin Immunol. 2020;146(6):1217-1270. doi:10.1016/j.jaci.2020.10.003 Accessed March 2, 2023.
3. Global Initiative for Asthma (GINA) Main Report. 2022 GINA Report, Global Strategy for Asthma Management and Prevention. <https://ginasthma.org/gina-reports> Accessed March 3, 2023.
4. Reddel, Helen K et al. "A Practical Guide to Implementing SMART in Asthma Management." The journal of allergy and clinical immunology. In practice vol. 10,1S (2022): S31-S38. doi:10.1016/j.jaip.2021.10.011 Accessed March 3, 2023.